DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 22 1994

Re: Neutrexin™
Docket No. 94E-0099

#13

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,376,858, filed by Warner-Lambert Company under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Neutrexin™, the human drug product claimed by the patent.

The total length of the regulatory review period for Neutrexin™ is 2,251 days. Of this time, 1,934 days occurred during the testing phase and 317 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 21, 1987.

   The applicant claims September 2, 1987, as the date the investigational new drug application (IND) for Neutrexin™ (IND 29,796) became effective. However, IND 29,796 was placed on clinical hold on March 30, 1987, within 30 days of being received by the agency on March 10, 1987. FDA records indicate that the IND effective date was October 21, 1987, the date IND 29,796 was removed from clinical hold.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 4, 1993.

   The applicant claims February 1, 1993, as the date the new drug application (NDA) for Neutrexin™ was initially submitted. However, FDA records indicate that the new drug application (NDA) for Neutrexin™ (NDA 20-326) was submitted on February 4, 1993.

3. The date the application was approved: December 17, 1993.

   FDA has verified the applicant's claim that NDA 20-326 was approved on December 17, 1993.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Francis J. Tinney
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